



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Application of:**

Hateboer et al.

**Serial No.:** 10/790,562

**Filed:** March 1, 2004

**For:** RECOMBINANT PROTEIN  
PRODUCTION IN A HUMAN CELL

**Confirmation No.:** 9903

**Examiner:** W. Schlapkohl, Ph.D.

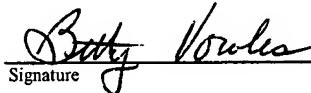
**Group Art Unit:** 1653

**Attorney Docket No.:** 2578-4038.3US

CERTIFICATE OF MAILING

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Signature \_\_\_\_\_  
Betty Vowles  
\_\_\_\_\_  
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of any cited foreign patents, publications, or pending unpublished U.S. applications are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

On May 24, 2005, Applicants submitted an Information Disclosure Statement. The Information Disclosure Statement mistakenly identified several documents with a pound (#) sign as having previously been submitted. The documents had not previously been submitted. Applicants hereby enclose the documents which should have been submitted with the

Information Disclosure Statement of May 24, 2005. Also enclosed is a replacement copy of PTO/SB/08.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
WO 95/05465	02-23-1995	Amgen Inc.
WO 98/18926	05-07-1998	G.D. Searle & Co.
WO 98/39411	09-11-1998	Baxter International Inc.
WO 98/44141	10-08-1998	The University of British Columbia
WO 99/05268	02-04-1999	Boehringer Mannheim GMBH
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WO 00/63403	10-26-2000	Introgen B.V.
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WO 2004/003176	01-08-2004	The Kenneth S. Warren Institute, Inc.
WO 2004/099396	11-18-2004	Crucell Holland B.V.
EP 0 411 678	02-06-1991	Genetics Institute, Inc.

Other Documents

BOUT et al., "Improved helper cells for RCA-free production of E1-deleted recombinant adenovirus vectors," Cancer Gene Therapy, 1996, pp. S24, Vol. 3, No. 6.

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FALLAUX et al., "New helper cells and matched early region 1-deleted adenovirus vectors prevent generation of replication-competent adenoviruses," Human Gene Therapy, Sept. 1, 1998, Vol. 9, No. 1, pp. 1909-1917. Abstract.

GRABENHORST et al., Construction of stable BHK-21 cells coexpressing human secretory glycoproteins and human Gal(beta-1-4)GlcNAc-R alpha-2,6-sialyltransferase alpha-2,6-Linked NeuAc is preferentially attached to the Gal(beta-1-4)GlcNAc(beta-1-2)Man(alpha-1-3)-branch of diantennary oligosaccharides from secreted recombinant beta-trace protein, Eur. J. Biochem, 1995, pp. 718-25, Vol. 232, No. 3, Berlin, Germany.

GRAND et al., "Modulation of the level of expression of cellular genes in adenovirus 12-infected and transformed human cells," Eur Mol Biol Organ J. 1986, 5 (6) 1253-1260. Abstract.

GRAND et al., "The high levels of p53 present in adenovirus early region 1-transformed human cells do not cause up-regulation of MDM2 expression," Virology, 1995, Vol. 210, No. 2, pp. 323-334. Abstract.

HOLLISTER et al., Stable expression of mammalian beta1,4-galactosyltransferase extends the N-glycosylation pathway in insect cells, Glycobiology, 1998, pp. 473-80, Vol. 8, No. 5, IRL Press, United Kingdom.

JENKINS et al., Getting the glycosylation right: Implications for the biotechnology industry, *Nature Biotechnology*, August 1996, pp. 975-81, Vol. 14, No. 8, Nature Publishing, US.

LOUIS et al., Cloning and Sequencing of the Cellular--Viral Junctions from the Human Adenovirus Type 5 Transformed 293 Cell Line, *Virology*, 1997, pp. 423-29, Vol. 233.

MINCH et al., Tissue Plasminogen Activator Coexpressed in Chinese Hamster Ovary Cells with alpha(2,6)-Sialyltransferase Contains NeuAc-alpha(2,6)Gal-beta(1,4)Glc-N-AcR Linkages, *Biotechnol. Prog.*, 1995, pp. 348-51, Vol. 11, No. 3.

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PAU et al., Abstract, The human cell line PER.C6 provides a new manufacturing system for the production of influenza vaccines, *Vaccine*, Mar. 21, 2001, pp. 2716-21, Vol. 19, No. 17-19.

PAZUR et al., Abstract, Oligosaccharides as immunodeterminants of erythropoietin for two sets of anti-carbohydrate antibodies, *Journal of Protein Chemistry*, November 2000, pp. 631-35, Vol. 19, No. 8.

SCHIEDNER et al., Abstract, Efficient transformation of primary human amniocytes by E1 functions of Ad5: generation of new cell lines for adenoviral vector production, 2000, *Hum. Gene Ther.* 11, 2105-2116.

STOCKWELL et al., High-throughput screening of small molecules in Miniaturized Mammalian Cell-based Assays involving Post-translational Modifications, *Chemistry and Biology*, February 1999, pp. 71-83, Vol. 6, No. 2.

WEIKERT et al., Engineering Chinese hamster ovary cells to maximize sialic acid content of recombinant glycoproteins, *Nature Biotechnology*, November 1999, pp. 1116-21, Vol. 17, No. 11, Nature Pub. Co., New York, NY, US.

YU et al., "Enhanced c-erbB-2/neu expression in human ovarian cancer cells correlates with more severe malignancy that can be suppressed by E1A," *Cancer Res.*, 1993, 53 (4) 891-8. Abstract.

ZHANG et al., Stable expression of human alpha-2,6-sialyltransferase in Chinese hamster ovary cells: functional consequences for human erythropoietin expression and bioactivity, BBA - General Subjects; 1998, pp. 441-52, Vol. 1425, No. 3, Elsevier Science Publishers, NL.

This Supplemental Information Disclosure Statement was previously filed. Applicants are now submitting copies. If the Office determines that a fee is due, please debit TraskBritt Deposit Account No. 20-1469 for the fee.

Respectfully submitted,



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Date: October 25, 2006  
ACT/alb  
Enclosures: Form PTO/SB/08  
Cited Documents



**Substitute for form 1449A/PTO**

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

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of 3

Attorney Docket Number

***Complete if Known***

Application Number	10/790,562
Filing Date	March 1, 2004
First Named Inventor	Hateboer et al.
Group Art Unit	1636
Examiner Name	W. Schlapkoh

Sheet

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of 3

2578-4038.3US

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		WO 95/05465	02-23-1995	Amgen Inc.		
		WO 98/18926	05-07-1998	G.D. Searle & Co.		
		WO 98/39411	09-11-1998	Baxter International Inc.		
		WO 98/44141	10-08-1998	The University of British Columbia		
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		WO 01/38362 A2	05-31-2001	Crucell Holland B.V.		
		WO 02/053580	07-11-2002	The Kenneth S. Warren Institute, Inc.		
		WO 03/038100 A1	05-08-2003	Crucell Holland B.V.		
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		WO 03/048348 A2	06-12-2003	Crucell Holland B.V.		
		WO 03/051927	06-26-2003	Crucell Holland B.V.		
		WO 2004/003176	01-08-2004	The Kenneth S. Warren Institute, Inc.		
		WO 2004/099396	11-18-2004	Crucell Holland B.V.		
		EP 0 411 678	02-06-1991	Genetics Institute, Inc.		

Examiner Signature		Date Considered	
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**\*EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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of

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*Complete if Known*

Application Number	10/790,562
Filing Date	March 1, 2004
First Named Inventor	Hateboer et al.
Group Art Unit	1636
Examiner Name	W. Schlapkohl
Attorney Docket Number	2578-4038 31JS

## OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BOUT et al., "Improved helper cells for RCA-free production of E1-deleted recombinant adenovirus vectors," <i>Cancer Gene Therapy</i> , 1996, pp. S24, Vol. 3, No. 6.	
		BOUT et al., "Production of RCA-free batches of E1-deleted recombinant adenoviral vectors on PER.C6," <i>Nucleic Acids Symp. Ser.</i> 1998, XP-002115716, pp. 35-36.	
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		CRONAN, Abstract, <i>Biotination of Proteins in-vivo a post-translational modification to label purify and study proteins</i> , <i>Journal of Biological Chemistry</i> , June 25, 1990, pp. 10327-33, Vol. 265, No. 18.	
		European Search Report 05 10 0732, April 7, 2005.	
		FALLAUX et al, "New helper cells and matched early region 1-deleted adenovirus vectors prevent generation of replication-competent adenoviruses," <i>Human Gene Therapy</i> , Sept. 1, 1998, Vol. 9, No. 1, pp. 1909-1917. Abstract.	
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		LOUIS et al., Cloning and Sequencing of the Cellular-Viral Junctions from the Human Adenovirus Type 5 Transformed 293 Cell Line, <i>Virology</i> , 1997, pp. 423-29, Vol. 233.	

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		Group Art Unit	1636
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Sheet	3	of	3
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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
		MINCH et al., Tissue Plasminogen Activator Coexpressed in Chinese Hamster Ovary Cells with alpha(2,6)-Sialyltransferase Contains NeuAc-alpha(2,6)Gal-beta(1,4)Glc-N-AcR Linkages, Biotechnol. Prog., 1995, pp. 348-51, Vol. 11, No. 3.	
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		ZHANG et al., Stable expression of human alpha-2,6-sialyltransferase in Chinese hamster ovary cells: functional consequences for human erythropoietin expression and bioactivity, BBA - General Subjects, 1998, pp. 441-52, Vol. 1425, No. 3, Elsevier Science Publishers, NL.	

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